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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,564	03/27/2006	Tetsuya Kuhara	TOYA108.014APC	7010

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
12/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/573,564	KUHARA ET AL.	
	Examiner	Art Unit	
	ROBERT LANDSMAN	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-12 and 18-22* is/are pending in the application.

4a) Of the above claim(s) *5-12 and 18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/8/07;11/28/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment filed 11/8/07 has been entered into the record.

B. Claims 2-12 and 18-22 are pending. Claims 2-4 and 22 are the subject of this Office Action.

2. Claim Objections

A. The objection to claims 2 and 3 is withdrawn in view of Applicants' cancellation of claim 1.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 2-4 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a drug combination comprising lactoferrin and (1) a TLR3 ligand (e.g. poly I:C) and wherein the drug combination is (2) effective in mice, does not reasonably provide enablement for a combination comprising lactoferrin and (1) any non-TLR3 ligand or (2) for use in animals other than mice, Including humans. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The breadth is excessive with regard to Applicants claiming a drug combination comprising lactoferrin along with any non-TLR3 ligand. The specification only provides guidance as to the use of polyI:C, which is a TLR3 ligand (see the Molecular Medicine, vol 40, 2003 reference on the 1449

submitted 6/12/06). Given the fact that polyI:C is the only TLR ligand exemplified, it is not predictable that any non-TLR ligand would have the claimed effect of proliferating NK cells.

Furthermore, the specification is only drawn to testing in mice and continually discloses that the invention is drawn to non-human animals. However, the claims are not limited to mice and, especially, not to non-human animals. Even if Applicants argue that experiments in mice are indicative of success in other animal species, they would still need to limit the claims to no-human animals, unless an argument can be made to the contrary.

For these reasons, the Examiner holds that undue experimentation is required to practice the claimed invention.

4. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 2-4 is withdrawn in view of Applicants' cancellation of claim 1. The Examiner agrees with Applicants that no separate rejection under 35 USC 102 was made over Wang et al.

5. Claim Rejections - 35 USC § 103

A. The rejection of claims Claims 2-4 over Wang in view of Schmidt has been withdrawn in view of a new rejection under 35 USC 103

B. Claims 2-4 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. in view of Schmidt et al and further in view of Decicco et al. The claims and the teachings of both Wang and Schmidt are seen on page 3 of the Office Action mailed 8/10/07. In that rejection it was stated that no dosages were taught by the references. However, upon further review, Wang do teach (page 1023, left column) that 300 mg/kg of lactoferrin was adminstered to mice from days 11-3 (9 days); therefore, meeting the limitations of the claims. Neither Wang nor Schmidt teach administering a TLR ligand at the claimed dosage or for the claimed time period.

However, Decicco do teach a ***single intraperitoneal administration*** of 20 micrograms pIC to 148 gram rats (see section entitled "Experimental Design for Animal Experiments"). This dose is

approximately 140 micrograms/kg/day as claimed by the instant invention. The motivation to combine these references is given on page 3 of the Office Action mailed 8/10/07.

For the record, it is noted that the claims do not require that the TLR ligand proliferate NK cells, only that the combination does. Therefore, even if Schmidt teaches activation and not proliferation of NK cells (though this point is not argued by Applicants), the combination of TLR ligand and lactoferrin would be expected to proliferate NK cells since it was know in the art that lactoferrin, itself, proliferates NK cells.

6. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern); alt F 10 AM – 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647